

## Appendix X: Analytica Model Users' Guide

The Analytica® file accompanying this document contains the computer simulation models used to support the findings of the risk assessment.

The file contains one main model, and five supplementary models. The models are:

Model	Description
RTE <i>Salmonella</i> Risk Assessment	The RTE <i>Salmonella</i> Risk Assessment module contains the core risk assessment model. It models RTE products from raw material contamination levels through to final production values to compute a total supply risk. At intermediate stages, the impacts of various scenarios and policies are considered.
Storage and Dose-Response Model	The Storage and Dose-Response Model is a supplementary model examining the contribution of growth during retail and consumer storage to the final doses consumed. It compares the probability of illness of a contaminated serving undergoing growth with a contaminated serving assuming zero growth, as well as low survival. The model uses a Beta-Poisson dose-response curve.
<i>Salmonella</i> Lethality Model	The <i>Salmonella</i> Lethality Model simulates achieved versus targeted lethality by accounting for process variability. It illustrates the importance of using the arithmetic mean instead of the log mean when calculating effective lethality.
Comparative Lethality Model	<p>The Comparative Lethality Model illustrates the challenges in establishing a relationship between <i>Salmonella</i> lethality targets and the corresponding lethality values for EHEC and Lm. It demonstrates the variability in lethality values achieved for major and sub populations using different reference temperatures by calculating the cumulative lethality achieved using a simple heating model.</p> <p>Only the data from one study is considered. The overall variability in D-values reported in the literature is greater than represented here.</p>
Single CFU Validation Model	The Single CFU Validation Model presents the rationale for assuming that servings still contaminated after lethality treatment will have at most one CFU prior to storage and growth.
Senftenberg Cocktail Model	The Senftenberg Cocktail Model evaluates the impact of including the Senftenberg strain of <i>Salmonella</i> in

	cocktails used to determine lethality values for heat treatments. It compares the effective D-values for less resistant strains with those of Senftenberg and mixtures of the two to determine the overall safety factor achieved by including Senftenberg in the cocktail in different proportions.
--	--

Each model is discussed in further detail below. For an overview on using the Analytica® software itself, please see the Analytica® Overview document.

## RTE Salmonella Risk Assessment

The RTE *Salmonella* Risk Assessment module contains the core risk assessment model. It models RTE products from raw material contamination levels through to final production values to compute a total supply risk. At intermediate stages, the impacts of various scenarios and policies are considered.

### Modifying Model Parameters and Viewing Results

This model contains several parameters that the user may modify.

Diagram - RTE Salmonella Risk Assessment

**Input Parameters**

Raw Material Factor Assignment	Edit Table
Lethality Standard Assignment	DetermTab
Lethality Scenario Options	All ▼
Compliance Factor Assignment	Edit Table
Thermal Process Safety Factor Assignment	Edit Table
Storage and Growth Factor Assignment	Edit Table
Reheating Factor Assignment	Edit Table
Include Re-heating	All ▼
Include Thermal Process Safety Factor	All ▼

**Results**

Product Risk (Cases per Mkg p.a.)	Result	mid
Product Risk (Cases p.a.)	Result	mid
Total Supply Risk (Cases p.a.)	Result	mid

Mechanics

Figure 1 RTE *Salmonella* Risk Assessment Input Screen

<b>Parameter</b>	<b>Description</b>
Raw Material Factor Assignment	Prevalence levels in raw RTE products are determined by the prevalence levels in the raw materials that make up that product. This table allows the user to assign the raw materials used to produce each RTE product. Values between 0 and 1 are valid. A value of zero indicates that the RTE product does not contain any of that specific raw material. A value of 1 indicates that the RTE only uses this one raw material. Some RTE products may contain fractions of two or more raw materials. The proportions assigned to each RTE product must sum to 1. E.g. a product may consist of 0.75 ground beef and 0.25 ground pork, but not 0.9 ground beef and 0.4 ground pork. (See figure below.)
Lethality Standard Assignment	This element allows the user to specify which lethality standard to apply to each RTE product. Current choices are between a 5-log and 6.5-log reduction. There are three scenarios to define: All 5 Log assigns a 5-log reduction to all products. All 6.5 Log assigns a 6.5-log reduction to all products. These should remain fixed. The last scenario, Split, assigns a mix of lethality standards to each product. This scenario can be used to compare policy alternatives to the baselines established in the 5 Log and 6.5 Log scenarios.
Lethality Scenario Options	Allows the user to select which lethality standard scenario(s) to include in the simulation. All includes them all. Otherwise, only the scenario selected will be included.
Compliance Factor Assignment	<p>The goal of including this factor is to describe the relationship between a performance standard and the Effective Lethality achieved.</p> <p>Compliance levels represent varying levels of compliance with a standard. They range from meeting or exceeded the standard, to bands of compliance below standard (e.g. Standard -1 to Standard -2 Log).</p> <p>Each product category is assigned a proportion to each compliance level, for each of the lethality standards. This pattern will impact on the effective lethality achieved for that product and standard.</p>
Thermal Process Safety Factor Assignment	The treatment of some RTE products may include a thermal process safety factor. This table allows the user to assign what distribution of safety factors apply for each RTE product. For example, 50% of ground beef patty supplies may include a Small safety factor while 50% include a Moderate safety factor (0.5, 0.5 respectively). Note: this element can be removed from the model by using the Include Thermal Process Safety Factor parameter described below.
Storage and Growth Factor Assignment	This table allocates the storage growth pattern appropriate to each RTE food. For example, Roast Beef is considered fully-

	cooked, uncured, non-shelf stable and so receives a factor of 1 in this column.	
Reheating Factor Assignment	This element assigns the relevant proportion of typical re-heating patterns associated with the RTE product. For example, ground beef patties may always be re-heated while beef bologna is rarely re-heated. Re-heating may reduce the overall risk associated with the RTE product. Note: this element can be removed from the model by using the Include Re-heating parameter described below.	
<b>Parameter</b>	<b>Description</b>	<b>Options</b>
Include Re-heating	This parameter allows the user to include the effects of re-heating or not. The option “All” allows the user to compare the results of both options.	All Include Exclude
Include Thermal Process Safety Factor	This parameter allows the user to include the effects of thermal process safety factors or not. The option “All” allows the user to compare the results of both options.	All Include Exclude

	Ground Beef	Ground Chicken	Ground Turkey	Ground Pork	Intact Beef	Intact Chicken	Intact Turkey	Intact Pork
Ground Beef Patties	1	0	0	0	0	0	0	0
Ground Chicken Patties	0	1	0	0	0	0	0	0
Pork Bologna	0	0	0	1	0	0	0	0
Beef Bologna	1	0	0	0	0	0	0	0
Turkey Breast (Intact)	0	0	0	0	0	0	1	0
Turkey Roll (Comminuted)	0	0	1	0	0	0	0	0
Beef Frankfurters	1	0	0	0	0	0	0	0
Pork Frankfurters	0	0	0	1	0	0	0	0
Turkey Frankfurters	0	0	1	0	0	0	0	0
Roast Beef (Intact)	0	0	0	0	1	0	0	0
Cooked Ham	0	0	0	0	0	0	0	1
Country Ham	0	0	0	0	0	0	0	1
Semi-Dry Fermented Beef/Pork Sausage	1	0	0	0	0	0	0	0
Dry Beef Fermented Sausage (Pepperoni)	0	0	0	0	1	0	0	0
Prosciutto	0	0	0	0	0	0	0	1
Beef Jerky	0	0	0	0	1	0	0	0
Turkey Jerky	0	0	0	0	0	0	1	0

**Figure 2 Raw Material Factor Assignment**

The user may generate several results from the input window as well. For all the results, the user may switch between graphical and numerical displays. The results of this model are not stochastic, so only mid values may be viewed.

<b>Result</b>	<b>Description</b>
Log Risk	The log risk associated with each RTE product per million kg. At this point, the value does not incorporate the actual total production mass for the RTE product.
Product Risk	The risk associated with the entire production mass of each

	RTE product individually, based on the total production mass and the log risk per million kg.
Total Supply Risk	The risk associated with the entire production mass of all RTE products combined.

## Model Structure

For details on the structure of the model, please review the contents of the Mechanics module in the Analytica® file.

## Storage and Dose-Response Model

The Storage and Dose-Response Model is a supplementary model examining the contribution of growth during retail and consumer storage to the final doses consumed. It compares the probability of illness of a contaminated serving undergoing growth with a contaminated serving assuming zero growth, as well as low survival. The model uses a Beta-Poisson dose-response curve.

### Modifying Model Parameters and Viewing Results

This model contains several parameters that the user may modify.

**Diagram - Storage and Dose-Response Model**

**Input Parameters**

Retail Storage Time Uncertainty Options	No Change
Retail Storage Time Distribution Options	Triangular
Retail Storage Temp Uncertainty Options	No Change
Retail Storage Temp Distribution Options	All
Consumer Storage Time Uncertainty Options	No Change
Consumer Storage Time Distribution Options	BetaPERT
Consumer Storage Temp Uncertainty Options	No Change
Consumer Storage Temp Distribution Options	All
Maximum Population Uncertainty Options	No Change
Min Growth Temp Uncertainty Options	No Change
Base EGR Uncertainty Options	All
Dose-Response Beta-Poisson Alpha Uncertainty Options	No Change
Dose-Response Beta-Poisson Beta Uncertainty Options	No Change

**Mechanics**

**Results**

Final Retail Population (CFU/Serving)	Calc	$\mu$
Final Consumer Population (CFU/Serving)	Calc	$\mu$
Probability of Illness	Calc	$\mu$

Figure 3 Storage and Dose-Response Input Screen

Parameter	Description	Options
Retail Storage Time Uncertainty	Users may use this parameter to shift the storage time parameters higher or lower. Shift options adjust all the parameters.	Shift Lower Lower ML No Change

	Lower and increase most likely (ML) only affect the most likely parameter, which do not apply when a Uniform distribution is selected.	Increase ML Shift Higher
Retail Storage Time Distribution	Users may select one of the distributions. Triangular biases the results towards the most likely temperature.	Uniform Triangular
Retail Storage Temp Uncertainty	Users may use this parameter to shift the storage temperature parameters higher or lower. Shift options adjust all the parameters. Lower and increase most likely (ML) only affect the most likely parameter, which do not apply when a Uniform distribution is selected. None of the parameters apply if the Empirical distribution is selected.	Shift Lower Lower ML No Change Increase ML Shift Higher
Retail Storage Temp Distribution	Users may select one of the distributions. Triangular biases the results towards the most likely temperature. The Empirical distribution reflects refrigerated storage only.	All Uniform Triangular Empirical
Consumer Storage Time Uncertainty	These parameters are functionally equivalent to the retail parameters, but apply to consumer storage. One difference is the addition of the Beta-PERT distribution for Consumer Storage Time Distribution.	Shift Lower Lower ML No Change Increase ML Shift Higher
Consumer Storage Time Distribution		Uniform Triangular BetaPERT
Consumer Storage Temp Uncertainty		Shift Lower Lower ML No Change Increase ML Shift Higher
Consumer Storage Temp Distribution		All Uniform Triangular Empirical
Maximum Population Uncertainty	The parameter alters the maximum pathogen population allowed in a single serving. This acts to put an upper bound on growth.	Shift Lower No Change Shift Higher
Min Growth Temp Uncertainty	This parameter alters the minimum growth temperature of the pathogen.	Shift Lower No Change Shift Higher



Base EGR Uncertainty	The parameter alters the base exponential growth rate (EGR) of the pathogen. Low Growth corresponds to half of normal.	Low Growth Shift Lower No Change Shift Higher
Beta-Poisson Alpha	This parameter alters the alpha parameter used to determine the Beta-Poisson dose-response curve.	Shift Lower No Change Shift Higher
Beta-Poisson Beta	This parameter alters the beta parameter used to determine the Beta-Poisson dose-response curve.	Shift Lower No Change Shift Higher

The user may generate several results from the input window as well. For all the results, the user may switch between graphical and numerical displays. For all the results, the user may also switch between aggregate and individual results.

<b>Result</b>	<b>Description</b>
Final Retail Population	Displays the final population after retail storage assuming an initial load of 1 CFU, and that growth occurs.
Final Consumer Population	Displays the final population after consumer storage assuming an initial load of the final retail population, and that growth occurs.
Probability of Illness	Shows the probability of illness of consuming a contaminated serving as determined by the Beta-Poisson dose-response curve for growth, no-growth (1 CFU dose), and low-survival (1 CFU dose-response reduced by a factor of 10) scenarios. The no-growth and low-survival probabilities of illness are dependent only on the Alpha and Beta parameters.

## Model Structure

For details on the structure of the model, please review the contents of the Mechanics module in the Analytica® file.

## Salmonella Lethality Model

The *Salmonella* Lethality Model simulates achieved versus targeted lethality by accounting for process variability. It illustrates the importance of using the arithmetic mean instead of the log mean when calculating effective lethality. It shows that if there is any process variability around the target lethality value, the effective lethality is always less than the target lethality even if the process can achieve better than target results with the same frequency as poorer than target results. This is implied by using the normal distribution to determine achieved lethality.

One way to mitigate against this effect is to apply a lethality offset to the target lethality to increase the overall process lethality target.

During each simulation iteration, the lethality value achieved is computed using a Normal Distribution with a mean of the target lethality, and a standard deviation computed using a coefficient of variation. The arithmetic mean of these lethality values (non-log scale) is used to determine the effective lethality (log scale).

## Modifying Model Parameters and Viewing Results

This model contains several parameters that the user may modify.

Diagram - Salmonella Lethality Model

**Input Parameters**

Target Lethality Options: All

Target Lethality Offset Options: None

Target Lethality COV Options: All

Pathogen Distribution Pattern Options: Evenly Distributed

Treatment Bin Lethality Offset Options: None

**Results**

Lethality Value Achieved: Calc  $\mu$

Effective Probability of Survival: Calc  $\mu$

Effective Lethality (Log CFU): Calc mid

Mechanics

Figure 4 Salmonella Lethality Input Screen

<b>Parameter</b>	<b>Description</b>	<b>Options</b>
Target Lethality	Log lethality target to consider	All 3 4 5 6 7
Target Lethality Offset	Used to add or subtract a fixed offset from the target lethality. The total of this value and the target value are used to determine the standard deviation from the COV. A moderate offset increase the process target by one log. A high offset increases the process target by two logs.	None Moderate High
Target Lethality COV	This parameter determines the COV used to compute the standard deviation for the normal distribution. Selecting All will allow comparison in the effective lethality achieved by different process variation levels.	All None Moderate High
Pathogen Distribution	<p>The model can also simulate the variability in the lethality achieved due to the geometry of the product and the distribution of the pathogens in the product. For example, a thick roast may experience much greater temperatures at the surface than at the core.</p> <p>This parameter determines how the pathogens are distributed in the product.</p>	Evenly distributed Primarily surface Primarily core
Treatment Bin Offset	This parameter determines if pathogens at different locations in the product experience higher than target lethality levels by applying a log increase in lethality to appropriate locations in the product. Setting this parameter to None will effectively exclude geometry from the calculations.	None Surface Higher

The user may generate several results from the input window as well. For all the results, the user may switch between graphical and numerical displays. For the first two, the user may also switch between aggregate and individual results.

<b>Result</b>	<b>Description</b>
---------------	--------------------

Lethality Value Achieved	Click on this element to view the lethality values achieved during each iteration of the simulation for the selected options. The higher the COV, the more variation. See the figure below for an example.
Effective Probability of Survival	This result shows the intermediate result of the probability of survival achieved.
Effective Lethality	This result shows the final result of the effective lethality computed by converting the mean of the effective probability of survival on the non-log scale to the log scale.

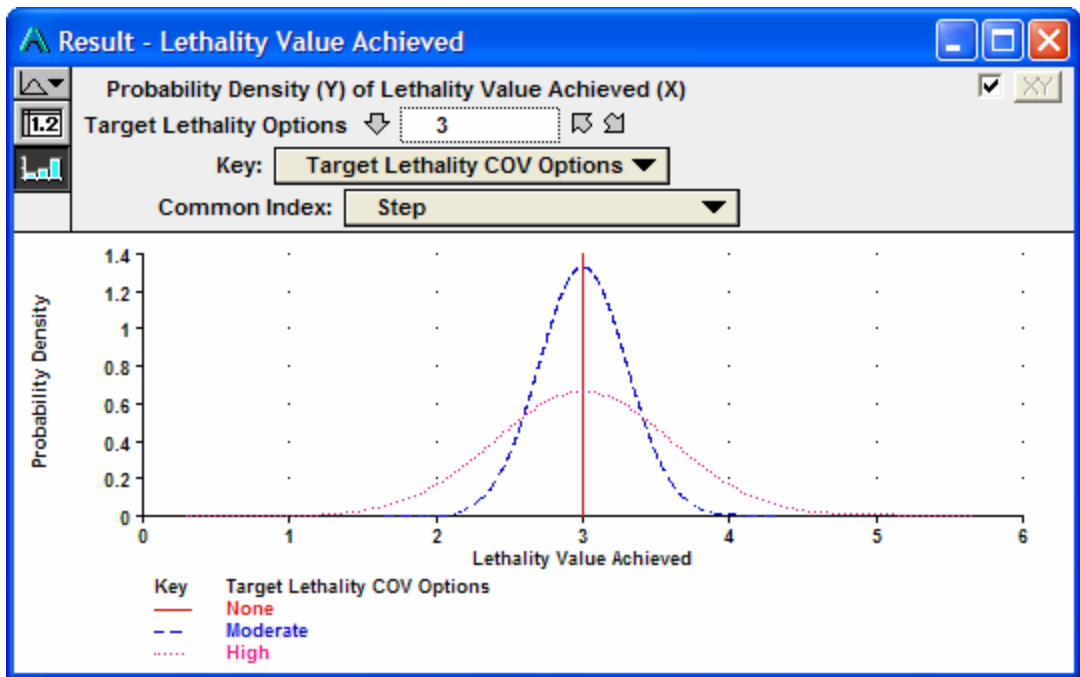


Figure 5 Lethality Value Achieved

## Model Structure

For details on the structure of the model, please review the contents of the Mechanics module in the Analytica® file.

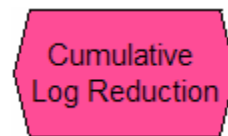
## Comparative Lethality Model

The Comparative Lethality Model illustrates the challenges in establishing a relationship between *Salmonella* lethality targets and the corresponding lethality values for EHEC and Lm. It demonstrates the variability in lethality values achieved for major and sub populations using different reference temperatures by calculating the cumulative lethality achieved using a simple heating model.

Only the data from one study is considered. The overall variability in D-values reported in the literature is greater than represented here.

## Modifying Model Parameters and Viewing Results

This model does not have any user-modifiable parameters. To view sample results for Cumulative Log Reduction, please select the module show at the right and click Ctrl-R, or select Show Result from the Results menu.



## Model Structure

The model is a dynamic model. That is, it models the cumulative log reduction achieved for each organism over time. To simplify comparison, a constant temperature of 65 °C is assumed. No initial contamination level is assumed for any of the organisms. Instead, a D-value is computed at the treatment temperature for each organism, for each of the reference D-values and z-values provided for both major and sub populations.<sup>1</sup> These D-values are then used to determine the cumulative log reduction achieved during the heating process. The model simulates variability in the D-values using the reference D-values and standard deviations to generate a Normal distribution of D-values.

The results show that the relative difference between organisms in log reductions achieved can vary depending on whether the major or subpopulation is considered, and which reference temperature is used to determine the reference D-value. For example, the following figures show that for the major populations *Salmonella* achieves the largest log reduction, while for the subpopulations, EHEC achieves the largest log reduction, and that the log reductions achieved by the major and subpopulations are significantly different.

---

<sup>1</sup> Juneja, Vijay K. 2003. A comparative heat inactivation study of indigenous microflora in beef with that of *Listeria monocytogenes*, *Salmonella* serotypes and *Escherichia coli* O157:H7. Submitted - Letters in Applied Microbiology.

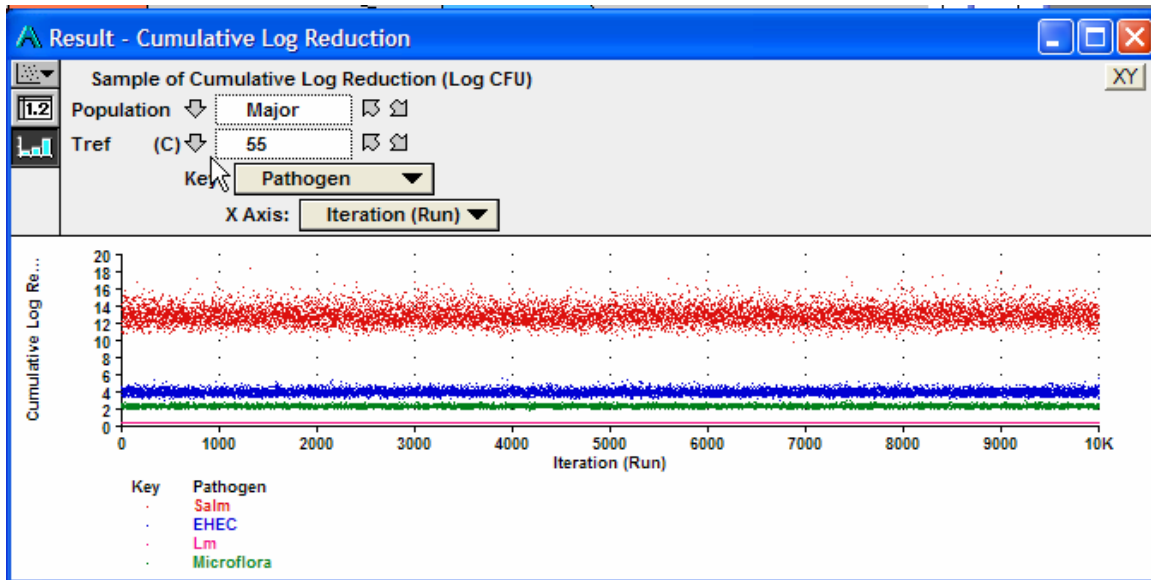


Figure 6 Cumulative Log Reduction - Major Population

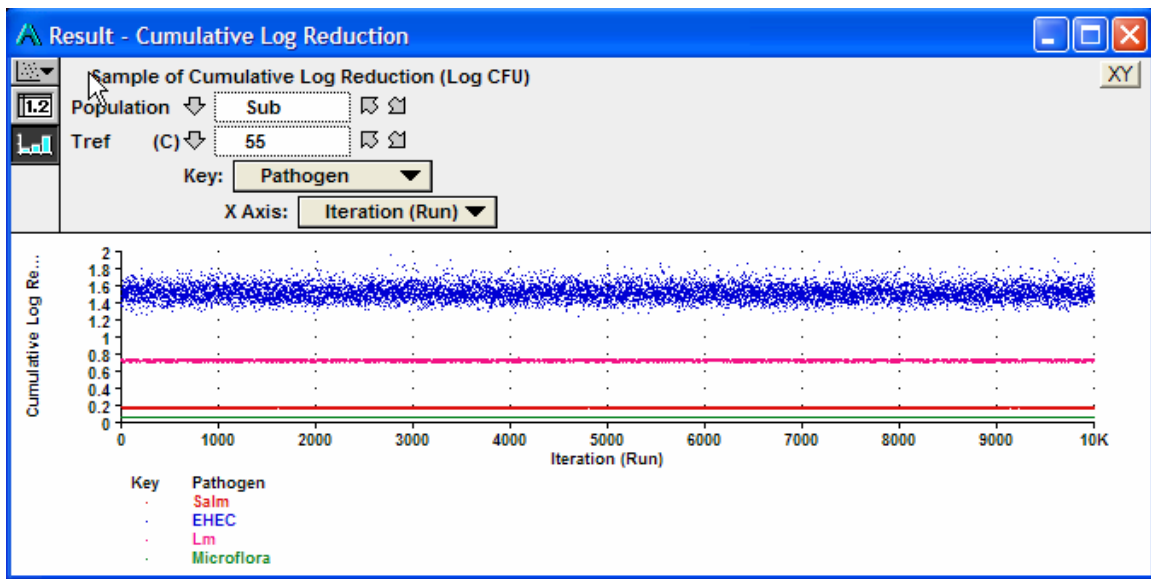


Figure 7 Cumulative Log Reduction - Subpopulation

This model captures only a small proportion of the variability noted in the literature.

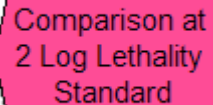
For details on the structure of the model, please review the contents of the Mechanics module in the Analytica® file.

## ***Single CFU Validation Model***

The Single CFU Validation Model presents the rationale for assuming that servings still contaminated after lethality treatment will have at most one CFU prior to storage and growth.

### **Modifying Model Parameters and Viewing Results**

This model does not have any user-modifiable parameters. To view sample results for a 2-Log reduction, please select the module show at the right and click Ctrl-R, or select Show Result from the Results menu.



Comparison at  
2 Log Lethality  
Standard

### **Model Structure**

The following model uses a binomial lethality survival model to determine the probability that:

- a) there are no surviving pathogens
- b) there is one surviving pathogen
- c) there are two surviving pathogens
- d) there are more than one surviving pathogens
- e) there are more than two surviving pathogens

The model examines all combinations of the following variables:

- a) Log Lethality values of 2, 3, 4, 5, 6 and 7
- b) Mean pathogen concentrations in raw materials of 0.001, 0.01, 0.1, 1, 10, and 100 CFU/g
- c) Serving sizes of 1, 10, 100, and 1000 g

Overall results indicate that if the log lethality value is the same as the log mean pathogen count in a serving, there will approximately be one surviving pathogen in 60% of the cases where pathogens survive, and two or less in 90% of the cases. For scenarios where the lethality value is one log higher than the mean count, there will be one surviving pathogen in 95% of the cases where pathogens survive and two or less in 99.9%. The results of this model support the assumption in the main model that any servings still contaminated after lethality treatment will likely only have a single pathogen remaining before storage and growth, and rarely more than two.

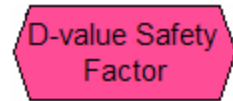
For details on the structure of the model, please review the contents of the Mechanics module in the Analytica® file.

## ***Senftenberg Cocktail Model***

The Senftenberg Cocktail Model evaluates the impact of including the Senftenberg strain of *Salmonella* in cocktails used to determine lethality values for heat treatments. It compares the effective D-values for less resistant strains with those of Senftenberg and mixtures of Senftenberg with each of the less resistant strains to determine the overall safety factor achieved by including Senftenberg in the cocktail in different proportions.

### **Modifying Model Parameters and Viewing Results**

This model does not have any user-modifiable parameters. To view sample results, please select the D-value Safety Factor module show at the right and click Ctrl-R, or select Show Result from the Results menu.



### **Model Structure**

For details on the structure of the model, please review the contents of the Mechanics module in the Analytica® file. The heat treatment calculations in this model are similar to those in the Comparative Lethality Model.